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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,543	01/08/2001	Richard A. Young	0399.1185-006	6739

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/28/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/756,543		YOUNG, RICHARD A.	
	Examiner		Art Unit	
	Michail A Belyavskiy		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002 and 06 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9 and 13</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's election of hsp70 mycobacterial heat shock protein as species of heat shock protein and protein as species of moiety in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-24 drawn to a method of delivering a moiety of interest into a cells, comprising contacting the cell with a complex comprising the moiety of interest covalently linked to a heat shock protein, wherein heat shock protein is a hsp70 mycobacterial heat shock protein and the moiety is a protein are under consideration in the instant application.

2. The specification on page 1, line 10 should be amended to reflect the status of the parent 09/025178 application.

3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved

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by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. The use of the trademark FIVOLL-PAQUE and MINI MACS have been noted in this application (page 19, line 25 and page 20, line 23). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The specification is objected to under 37 CFR 1.821(d) for failing to disclose SEQ ID NO, for the amino acid sequence disclosed on page 23, line 12.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. For example, on Page 23, line 12 the specification disclosed: "T2-K^b cells ____ ____". Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzue et al. (1996, Reference AZ3 in IDS) as evidenced by Srivastava et al (1994, Reference AV4 in IDS).

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Suzue et al. teach a method of delivering a moiety of interest into an antigen presenting cell of an individual, comprising contacting a cell with a complex, comprising an HIV covalently linked to mycobacteria heat shock protein 70 (see entire document, Abstract in particular). Suzue et al. teach a fusion protein comprising mycobacterial hps70 – HIV-1 p24 (see Materials and Methods in particular, pages 873 to 875). Suzue et al. also teach that administration of this fusion protein to mice induces a strong immune response (see page 875, 1st column and page 876 2nd column in particular). Suzue et al. also teach that the coupling must be covalent in order to be maximally efficacious (see page 876, 2nd column in particular).

The mechanism that the complexes of HSP's with antigens are processed by uptake into macrophages or other antigen presenting cells with re-expression of antigenic peptides on the surface of the antigen presenting cells for presentation to T cells (in particular Srivastava et al., page 729, 2nd column, lines 20-22 , 25-30 and page 730, 1st column , lines 7-11 and 19) is inherent in the structure of the hsp-antigen conjugate and the general properties of the immune response. If an antigen is immunogenic then it is taken up by cells as per immediately above encompassing claims 1, 9, 13 and 21. It was known at the time the invention was made that the immunogenicity of a heat shock protein-antigen complex was a function of the uptake of the complex by antigen presenting cells (see Srivastava et al. above) thus encompassing claims 5.

The reference teachings anticipate the claimed invention.

9. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrios et al.(1992, Reference AU in IDS) as evidenced by Srivastava et al (1994, Reference AV4 in IDS).

Barrios et al. teach the method of delivering a protein to an individual in such ways to induced an immune response using a protein covalently coupled to a mycobacterial hsp70 (see entire reference, Abstract in particular). Barrios et al. teach the making of a glutaraldehyde covalently crosslinked complex of mycobacterial hsp70 and proteins (see pages 1366 in particular). Barrios et al. teach that administration of this complex into mice induces a strong immune response and that the coupling must be covalent in order to be maximally efficacious (see page 1386 in particular). Barrios et al. teach that the effect observed may be due to increased cellular uptake of the antigen complex by antigen processing cells because of the chaperone function of the HSP70 (see page 1371 in particular).

The mechanism that the complexes of HSP's with antigens are processed by uptake into macrophages or other antigen presenting cells with re-expression of antigenic peptides on the surface of the antigen presenting cells for presentation to T cells (in particular Srivastava et al., page 729, 2nd column, lines 20-22 , 25-30 and page 730, 1st column , lines 7-11 and 19) is inherent in the structure of the hsp-antigen conjugate and the general properties of the immune response. If an antigen is immunogenic then it is taken up by cells as per immediately above encompassing claims 1, 9, 13 and 21. It was known at the time the invention was made that the immunogenicity of a heat shock protein-antigen complex was a function of the uptake of the

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complex by antigen presenting cells (see Srivastava et al. above) thus encompassing claims 5 and 17.


The reference teachings anticipate the claimed invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
January 27, 2003


CHRISTINA CHAN
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TECHNOLOGY CENTER 1600